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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/681,061

10/07/2003

Robert E. Sievers

45-99A

7845

23713

7590

04/21/2006

GREENLEE WINNER AND SULLIVAN P C
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EXAMINER

ZARA, JANE J

ART UNIT

PAPER NUMBER

1635

DATE MAILED: 04/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/681,061

Applicant(s)

SIEVERS ET AL.

Examiner

Jane Zara

Art Unit

1635

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 October 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>2/04</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

This Office action is in response to the communication filed 10-7-03.

Claims 1-6 are pending in the instant application.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-6 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to particles comprising substances either soluble in supercritical fluid, near critical fluid, mixtures thereof, or substances soluble or suspendable in aqueous solutions, and optionally further comprising one or more of group consisting of excipients, stabilizers, bulking agents and surfactants. The specification teaches a method of forming particles comprising forming a substance by combining the substance (e.g. 0.1 mg/ml lysozyme or LDH) in different formulations (100mM KPO₄ optionally with 10% mannitol, or optionally with 10% sucrose with or without Tween 20) and exposing it to supercritical or near critical fluid CO₂ (T>32⁰C, P=1500 psi), reducing the pressure, forming droplets and passing the droplets through a heated flow of drying gas. The genus

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of substances claimed encompasses an expansive myriad of structures (e.g. thousands and thousands of species) and the specification and claims do not adequately teach a representative number of species for the very broad genus claimed. Concise structural features that could distinguish structures within the broad genus claimed from others are missing from the disclosure. No common structural attributes identify the members of the claimed genus, and distinguish members within the claimed genus from those outside of the claimed genus. One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus claimed. Thus, Applicant was not in possession of the claimed genus.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2 and 4-6 are rejected under 35 U.S.C. 102(a) as being anticipated by Sloan et al.

Sloan et al (ISASF 6th Meeting on Supercritical Fluids – Chemistry & Materials, April 10-13, pages 169-174, 1999) teach fine dry particles comprising pharmaceutical substances either soluble or suspendable in aqueous solutions,

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which substances have at least 90% of the original pharmaceutical activity, and which particles are between 0.1 to 10 microns in diameter and a skin thickness of 0.1-.001 of the diameter, a moisture content between 0.1-10% and a bulk density between 0.1-1.5 g/cm³, and which pharmaceutical substances comprise protein or DNA (see esp. fig. 2 on p. 171, table 1 on p. 173, text on pp. 172-3).

Claims 1-6 are rejected under 35 U.S.C. 102(a) as being anticipated by Reverchon.

Reverchon (J. Supercritical Fluids, Vol. 15, pages 1-21, 1999) teach fine dry particles comprising pharmaceutical substances either soluble or suspendable in aqueous solutions, which substances have at least 90% of the original pharmaceutical activity, and which particles are between 0.1 to 10 microns in diameter and a skin thickness of 0.1-.001 of the diameter, a moisture content between 0.1-10% and a bulk density between 0.1-1.5 g/cm³, and which pharmaceutical substances comprise a physiologically active material and which particles optionally further comprise a surfactant or excipient between .001-75% of the dry particle weight (see esp. text and table 3 on p. 6, text, figs. 3 and 4 on p. 7, text on p. 8, table 4 on p. 9, first full paragraph on p. 10, fig. 10 on p. 13, fig. 13 on p. 14, fig. 14 on p. 15).

Claims 1, 2 and 4-6 are rejected under 35 U.S.C. 102(b) as being anticipated by Winters et al.

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(pages 586 - 594)

Winters et al (J. Phar. Sci., Vol. 85, No. 6, 1996) teach fine dry particles comprising pharmaceutical substances either soluble or suspendable in aqueous solutions, which substances have at least 90% of the original pharmaceutical activity, and which particles are between 0.1 to 10 microns in diameter and a skin thickness of 0.1-.001 of the diameter, a moisture content between 0.1-10% and a bulk density between 0.1-1.5 g/cm³, and which pharmaceutical substances comprise proteins (see esp. the abstract and text on p. 586, table 4 and text on p. 592, fig. 9 on p. 593, fig. 10 and text on p. 594).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

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Claims 1-6 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-28 of U.S. Patent No. 6,630,121. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are drawn to products obtained by the process of claimed methods in claims 1-28 of U.S. Patent No. 6,630,121.

Conclusion

Certain papers related to this application may be submitted to Art Unit 1635 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. 1.6(d)). The official fax telephone number for the Group is **571-273-8300**. NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

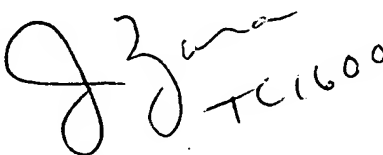
Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Jane Zara** whose telephone number is **(571) 272-0765**. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang, can be reached on (571) 272-0811. Any inquiry regarding this application should be directed to the patent analyst, Katrina Turner, whose telephone number is (571) 272-0564. Any inquiry of a general

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nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jane Zara
4-14-06

Handwritten signature of Jane Zara in cursive, followed by the text "TC1600" in a similar handwritten style.

JANE ZARA, PH.D.
PRIMARY EXAMINER